Remarks

Claims 39-42, 48-51, 54-56, 67-73, 75, 78-80, 82-84, 86, 88-90, 92, 93, 95, 96, 98-162, 164-174, 176-213 and 216-231 are presently pending in the subject application.

Reconsideration and allowance in view of the above amendments and the following remarks are respectfully requested.

To address the Examiner's rejection of claims 167, 214 and 215 under 35 U.S.C. § 112, second paragraph, Applicants have cancelled claims 214 and 215 herein and amended claim 167 to replace the phrase "the sequence perfectly complementary thereto" with the phrase "a sequence of the same length and fully complementary thereto." Applicants amendment to claim 167 is also believed to overcome the Examiner's rejection of claim 167 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,521,300 (Shah *et al.*) Accordingly, Applicants respectfully request withdrawal of the Examiner's rejection of claims 167, 214 and 215 as being indefinite and claim 167 as being anticipated.

Claims 48-51, 54, 93, 99, 220 and 221 stand objected to by the Examiner as being dependent upon a rejected base claim. Applicants submit that the claims from which the objected claims depend are patentable for the reasons set forth below. Accordingly, withdrawal of this objection is respectfully requested.

Applicants note with appreciation the Examiner's indication that claims 42, 55, 56, 75, 78-80, 82, 83, 95, 96, 100-149, 151-157, 164-166, 169-172, 174, 177-179, 185, 187-191, 195, 196, 199-203, 216-219 and 227-231 are allowed.

As a clarification, Applicants wish to note for the record that use of the phrase "hybridizes with specificity" in the claims is intended to indicate that the referenced hybridization probe binds to nucleic acid from any of the tuberculosis mycobacteria, which is a group comprised of the members of the *M. tuberculosis* complex, as opposed to nucleic acid from non-tuberculosis mycobacteria. This interpretation is supported by those skilled in the art who have concluded that treatment of the members of the *M. tuberculosis* complex as distinct species is unsupported. *See* Attachment A, GEORGE P. KUBICA, THE MYCOBACTERIA: A SOURCE BOOK, pp. 42-43 (1984).

Interview Summary

Applicants wish to thank the Examiner for permitting an in-person interview with the undersigned on October 7, 2003. During the granted interview, Applicants' representative addressed the Examiner's rejection of claims 39-41, 67-73, 84, 86, 88-90, 92, 98, 150, 158-162, 168, 173, 176, 180-184, 186, 192-194, 197, 198, 204-213 and 222-226 under 35 U.S.C. § 103(a). Applicants' representative first noted that the selection of an amplification oligonucleotide or set of amplification oligonucleotides is dependent upon the identification of a region within the target nucleic acid that is determined to be specific for the intended target organism or group of organisms. To identify such a region, it is customary to compare sequence information derived from the intended target and other closely related organisms to ensure specificity of an oligonucleotide probe for the target nucleic acid within the test sample milieu. This customary design approach was practiced by the authors of the Böddinghaus reference cited by the Examiner, who disclose comparing rRNA sequences from a large number of *Mycobacterium* species to identify oligonucleotides specific at a genus, group or species level. *See* abstract and Table 1 of Böddinghaus. It was further pointed out that the activities disclosed in the Suzuki *et al.* reference cited by the Examiner do not contravene this practice, as Suzuki was only concerned with analyzing the structure of the 16S rRNA gene from *Mycobacterium bovis* BCG. While Suzuki does disclose comparing the 16S rRNA gene sequence of *M. bovis* BCG with those of *Escherichia coli* and *Streptomyces lividans*, there is no suggestion to design probes or primers to any region of the 16S rRNA gene sequence of *M. bovis* BCG or that a probe to the region identified by the Examiner would be useful in the specific detection of *M. bovis* BCG. And, as stressed in Applicants' Reply dated January 28, 2003, no reasoning has been presented for only distinguishing between nucleic acid derived from *M. bovis* BCG over nucleic acid derived from organisms which are not phylogenetically near to *M. bovis* BCG, such as *E. coli* and *S. lividans*. On this basis, Applicants representative submitted that the oligonucleotides recited in the rejected claims had an unexpected benefit of amplifying *Mycobacterium tuberculosis* nucleic acid in a region permitting the specific detection of *M. tuberculosis* in a test sample. Accordingly, Applicants respectfully request withdrawal of the Examiner's patentability rejection.

Conclusion

Applicants submit that the subject application is in condition for allowance and Notice to the effect is respectfully requested.

Please charge any fees due in connection with this Reply, including a one-month extension of time, to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

Certificate of Transmission

I hereby certify that this correspondence (and any referred to as attached) is being sent by facsimile to 703-872-9306 on the date indicated below to the Commissioner for Patents, Alexandria, Virginia 22313-1450.

Respectfully submitted,

Dated: October 17, 2003 By: _____

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ATTACHMENT A